

# Remarks

# PhRMA

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**PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA**

**PRESENTATION ON FDA'S PROPOSED RULE  
DISSEMINATION OF INFORMATION ON UNAPPROVED/NEW USES  
FOR MARKETING DRUGS - 63 Fed. Reg. 31143, June 8, 1998**

**FDA PUBLIC MEETING  
JULY 8, 1998, 1:30 - 4:30 p.m.**

Snow Room, Cohen Building, 330 Independence Ave., S.W., Washington, D.C.

PhRMA appreciates the opportunity to participate in this "Single Issue Focus Meeting" on FDA's proposed rule to implement the dissemination provision of the FDA Modernization Act of 1997 (FDAMA section 401, codified in the FD&C Act as a new Subchapter D, "Dissemination of Treatment Information," sections 551-557). Let me first note, however, that while we strongly support the diligence with which FDA has undertaken to implement the many provisions of FDAMA, it is unfortunate that inadequate notice was given of this important public meeting (which was announced just a week ago Tuesday on the eve of the July 4 holiday weekend; 63 Fed. Reg. 35551, June 30, 1998).

I am appearing today on behalf of America's leading research-based pharmaceutical and biotechnology companies. In 1998 our members will spend almost 20% of overall sales on R&D - more than \$20 billion; that compares with an average for all U.S. industry of only 3.4% of sales. Given the industry's key role in adding new medicines and cures to the nation's medicine chest, we are also pleased to support FDA's prescription drug review and approval program through the user fee program, which was also renewed as part of FDAMA; in 1998 our members will contribute over \$120 million in user fees to support FDA.

Dissemination section 401, one of the more important, and most detailed, provisions of FDAMA, was intended by Congress to balance two objectives: one, to facilitate the sharing of important treatment information with health care providers to enable better patient care in accordance with current medical knowledge, and two, to ensure that research leading to new labeled uses continues to be undertaken. This important provision arose from a bipartisan agreement that was reached a year ago this very month, following a dialogue that included Secretary Shalala, as well as Senators Mack, Kennedy, Frist, Dodd, Wyden and Boxer.

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Last July Senator Kennedy praised the fair balance struck by the compromise that came to be embodied in section 401. We are concerned, however, that FDA's June 8 proposal not only fails to implement this fair balance, but actually threatens the real-world utility of section 401. The reason for this concern is that the proposed rule goes beyond the carefully-defined statutory scheme to impose significant unauthorized requirements and constraints.

PhRMA will be submitting extensive and detailed comments to the docket by the July 23 deadline. Our concerns with the proposal are exemplified by the following:

- **The Proposal Confuses Dissemination with Promotion.** Notwithstanding the clear intent of Congress and the language of section 401, FDA is proposing to erect burdensome and extremely restrictive barriers that are seemingly intended to inhibit (not facilitate) the dissemination of important medical and scientific information on new treatment uses. It is as if the Agency were attempting to establish rules for off-label use *promotion* (as indeed FDA stated – erroneously – in its notice for this meeting on the FDA Website Home Page).
- **The Proposal Virtually Bans Reference Texts, and Overly Restricts Journal Articles.** FDA's proposal would prevent a manufacturer from disseminating a whole category of information that Congress intended to allow – reference texts. (No reference text reports individual clinical investigations in the "reasonably comprehensive manner" proposed by FDA). The bar is also needlessly high for peer-reviewed journal articles. For both reference texts and journal articles the statute only requires that they be "about a clinical investigation . . . that would be considered scientifically sound by experts." The language of the FDA proposal for a "reasonably comprehensive presentation of the study design, conduct, data, analyses and conclusions" could be read to impose an impractical level of detail.
- **The Proposal Provides an Unrealistic Exemption for Economically Prohibitive Supplements.** The statute provides an exemption from the requirement of filing a supplement on a new use on the grounds that it would be "economically prohibitive." While the circumstances that justify such exemptions were intended by Congress to be limited, the FDA proposal is unrealistically narrow, to the point of preventing manufacturers from ever disseminating information in the case of products for which it makes no economic sense to pursue a supplement.
- **The Proposal Would Require Unduly Restrictive Mandatory Statements.** The proposal would mandate a single set of disclaimers and the manner in which they are displayed for all cases, even though the statute requires only that the mandatory disclaimers be "prominently displayed." This is an

unnecessary level of regulation that will interfere with a manufacturer's ability to disseminate information in a manner appropriate for a particular treatment and product.

- **The Proposal Defines "New Use" So Broadly That Information on Approved Uses Could Potentially Fall within the Regulations.** The proposal defines new use to include a new age group, another patient subgroup not explicitly identified in the current labeling, and comparative claims to other agents for treatment of the same condition. This is not authorized by the statute; where claims regarding patient subgroups or comparative claims are otherwise permitted independent of section 401, they should not fall within the elaborate requirements for dissemination of new/unapproved uses. (Background: if a drug's approved indication contains no patient age limitation, statements describing the use of the drug in that indication in a particular patient population should not be considered a new use unless the manufacturer makes claims of special or unique safety/effectiveness in the subgroup; similarly, statements concerning a study comparing one drug to another with regard to an approved indication should not be deemed to describe a new use.)

Thank you for the opportunity to present these preliminary summary comments today. PhRMA submissions to FDA regarding FDAMA implementation are available on the PhRMA website, [www.phrma.org](http://www.phrma.org). These include a recommended approach for implementing section 401 (May 29, 1998), and a letter from PhRMA President Alan Holmer to FDA Acting Commissioner Friedman addressing immediate concerns with FDA's June 8 dissemination proposal (June 26, 1998).